REMARKS

Claims 17-33 are pending in the application. New claims 34 and 35 have been added to the application. Therefore, claims 17-35 are at issue.

Support for new claim 34 can be found in the specification, for example, at page 5, lines 10-31; page 11, line 41 through page 12, line 7; and Examples 1 and 2 at pages 17-19. Support for new claim 35 can be found in the specification at page 7, line 41 through page 8, line 2; page 10, lines 27-34; and page 11, lines 18-23.

The claims have been amended to clarify the invention and to recite a particle size in the range of 45 to 1000 μm. Claim 1 has been amended to recite swellable hydrogel-forming particles comprising a swellable hydrogel-forming polymer and at least one hydrophilic polymer of dendritic structure (dendritic polymer). Claim 33 has been amended to clarify the term "hygiene article". New claims 34 and 35 recite preferred embodiments of the invention wherein the dendritic polymer is present on the surfaces of the polymer particles (claim 34) and the swellable hydrogel forming polymer comprises a crosslinked, partially neutralized polyacrylic acid (claim 35). The amendments and new claims 34 and 35 are fully supported by original claim 26 and the specification at page 1, lines 17 and 18; page 13, lines 11-13; page 5, lines 10-15; page 11, lines 18-23; and Examples 1 and 2 at pages 17-19.

Claims 17-33 stand rejected under 35 U.S.C., second paragraph, as being indefinite. The examiner considered independent claim 17 indefinite because it was unclear whether the invention is directed to a copolymer of a mixture of polymers. Claim 17 has been amended as described above to clarify that the claimed invention is a mixture of swellable hydrogel-forming polymer particles and a dendritic polymer. New claim 34 recites that the dendritic polymer is present on the surfaces of the swellable polymer particles. As noted by the examiner, these features are made clear in Examples 1 and 2 of the specification.

The examiner also notes that claim 26 contains a typographical error in reciting a dependence from claim 1. Applicants have amended claim 26 to depend from claim 17 thereby correcting the typographical error.

In view of the amendments to claims 17 and 26, it is submitted that the rejections of claim 17-33 under 35 U.S.C. §112, second paragraph, have been overcome and should be withdrawn.

Claims 17, 18, 20, and 31-33 stand rejected under 35 U.S.C. §102(b) as being anticipated by, or alternatively under 35 U.S.C. §103 as being obvious over, Winterton et al. U.S. Patent Publication No. 2003/0134132 ('132 publication). Applicants traverse this rejection.

The '132 publication is directed to an ophthalmic device, such as a contact lens, having a lubricious coating. The examiner relies upon Example 2 of the '132 publication at paragraphs [0136]-[0140]. In this disclosure, the '132 publication teaches a contact layer having *multiple* bilayers of a polyamidoamine (PAMAM) dendrimer and a polyacrylamide-co-poly(acrylic acid) copolymer (PAAm-co-PAA). At paragraph [0138], the '132 publication teaches a coating having "multiple bilayers of PAMAM/PAAm-co-PAA" on a soft contact lens of fluorosiloxane. The contact lens is alternatively dipped in a PAAm-co-PAA solution and a PAMAM solution about 10 to about 20 *times* to coat the fluorosiloxane with multiple alternate layers of PAAm-co-PAA and PAMAM. Also see '132 publication, [0066].

The present claims differ significantly from the disclosure of the '132 publication such that a rejection under 35 U.S.C. §102(b) cannot be maintained. It is axiomatic that "[A]nticipation requires a showing that each limitation of a claim is found in a single reference, either expressly or inherently." *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006). With further respect to a rejection under 35 U.S.C. §102(b), MPEP §2131 states:

> "TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM
>
> 'A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' *Verdegaal Bros. v. Union Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)...'The identical invention must be shown

> in as complete detail as is contained in the...claim.' *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. In *re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)."

The '132 publication fails to meet this strict standard with respect to the present claims.

First, claim 17 recites swellable hydrogel-forming polymer *particles* having a particle size of about 45 to 1000 μm. The '132 publication fails to teach or suggest particles, but teaches multiple bilayers of a coating on a fluorosiloxane.

Second, the PAAm-co-PAA copolymer disclosed in the '132 publication is *dissolved* in water and therefore cannot be crosslinked. Swellable hydrogel forming polymers are not water soluble and are crosslinked. For example, see new claim 35.

Third, the examiner's comments that the amount of dendrimer present in the coating of the '132 publication "implicitly" is present in a low weight amount of less than 10 wt% is totally unsupported. The examiner, not the applicants, bears the burden of demonstrating that the claims are anticipated. Neither the examiner nor the '132 publication meets this burden. The reference teaches *multiple* bilayers of the two polymers thereby negating the examiner's bald statement. In addition, to support an anticipation rejection under 35 U.S.C. §102(b) the *identical* invention must be shown in as complete detail as is contained in the claim. The examiner *cannot* rely on an inherency theory because multiple bilayers of the '132 publication do not *necessarily* contain less than 10 wt% of the dendritic polymer.

With respect to claims 31 and 32, the '132 publication is directed to contact lenses which do not contact blood or urine. With respect to claim 33, this claim has been amended to clarify the "hygiene article". The term clearly does not encompass the contact lenses of the '132 publication.

For all the reasons set forth above, it is submitted that differences exist between claims 17, 18, 20, and 31-33 and the '132 publication such that a rejection under 35

U.S.C. §102(b) cannot be maintained. It is further submitted that the differences are non-obvious differences.

The coated contact lenses of the '132 publication are substantially different from the claimed swellable hydrogel-forming polymer particles, and fail to render the present swellable hydrogel-forming polymer particles obvious under 35 U.S.C. §103.

To establish a *prima facie* case of obviousness, three requirements must be satisfied. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was *an apparent reason* to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to *identify* a *reason that would have prompted a person of ordinary skill in the relevant field to combine the elements* in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (emphasis added, *KSR*, *supra*). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. In *re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

As recently articulated by the Court of Appeals for the Federal Circuit in *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.*, 86 USPQ 2d, 1196, 1201-2 (Fed. Cir. 2008):

> "As this court has explained, however, a flexible TSM test remains the primary guarantee against a non-statutory hindsight analysis such as occurred in this case. *In re Translogic Tech., Inc.* 504 F.3d 1249, 1257 [84 USPQ 2d 1929]

(Fed. Cir. 2007) ("[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention.)."

The '132 publication is directed to contact lenses having a lubricous coating applied thereto. The reference fails to teach or suggest, or even consider or address, hydrogel-forming polymer particles of a specific particle size range.

The '132 publication provides no apparent reason for a person skilled in the art to combine the elements in a way the claimed invention does, i.e., there is no apparent reason from the cited reference to coat hydrogel-forming polymer particles. The reference merely discloses bilayer coatings on a contact lens. In addition, the dendrimer of the '132 patent is coated onto a coating of a water *soluble* polymer, not a water swellable polymer.

The '132 publication also fails to teach all of the presently claimed features. The reference is not remotely related to swellable, hydrogel forming polymers *or* particles. The '132 publication is limited to multiple bilayer coatings of a water soluble polymer and a dendritic polymer on a contact lens to increase lubricity. The reference fails to teach or suggest water swellable polymer particles containing a dendritic polymer wherein the amount of fine sized particles, even after mechanical exposure, is substantially reduced (see specification, page 1, lines 32-40; page 2, lines 1-4; page 2, line 41 through page 3, line 8; page 13, lines 26-28; and Table 1 at page 19). The reduction in an amount of fine sized polymer particles is both unexpected and unpredicted in view of the '132 publication.

The prior discussion with respect to the rejection of claims 17, 18, 20, and 31-33 under 35 U.S.C. §102(b) provides additional reasons why these claims would not have been obvious over the '132 publication under 35 U.S.C. §103. Accordingly, it is submitted that, for all the reasons set forth above, the rejection of claims 17, 18, 20, and 31-33 under 35 U.S.C. §103 over the '132 publication should be withdrawn.

Claims 17-19, 21, 22, 24-27, 29, and 33 stand rejected under 35 U.S.C. §103 as being unpatentable over Staples et al. U.S. Patent 5,994,440 ('440) in view of a Hult publication (Hult). Applicants traverse this rejection.

The '440 patent discloses water-absorbent particles coated with a dedusting agent. The dedusting agents are water-soluble, lower aliphatic polyols or lower polyalkylene glycols ('440 patent, column 7, lines 22-42). The '440 patent fails to teach or suggest a dendritic polymer.

The Hult publication is an excerpt from the *Encyclopedia of Polymer Science and Technology* directed to hyperbranched polymers. The reference generally discusses dendritic polymers, including aliphatic polyesters, such as the BOLTORN® products available from Perstorp AB, Sweden. At page 10 of the Hult publication, the author states that

> "[N]umerous applications have been suggested for hyperbranched polymers but few have reached commercial exploitation. Only a few papers have been published where a certain application of a hyperbranched polymer has been addressed."

Accordingly, although dendritic polymers are known, wide use of such polymers has not been achieved.

Furthermore, the *Encyclopedia of Polymer Science and Technology*, under the heading "Aliphatic Polyesters", discloses dendritic polymers having hydroxy functionalities, e.g., the BOLTORN® series of polymers. The properties of BOLTORN® polymers are available, and it is noted that the polymers are "partly soluble in" to "not miscible with" water as set forth in the following table:

	Water Solubility	Molecular Weight
BOLTORN® H20	Partly soluble	2,100 g/mole
BOLTORN® H2004	Not miscible or difficult to mix	3,200 g/mole
BOLTORN® H311	Not miscible or difficult to mix	5,700 g/mole
BOLTORN® P1000	Partly miscible	1,500 g/mole
BOLTORN® P500	Partly miscible	2,000 g/mole
BOLTORN® U3000	Not miscible or difficult to mix	6,500 g/mole
BOLTORN® W3000	Partly miscible	9,000 g/mole

After reading the '440 patent and the Hult publication, *and* considering additional information relating to the BOLTORN® polymers, a person skilled in the art would

have had no apparent reason to substitute a claimed dendritic polymer of partial to no water solubility for the water-soluble dedusting agents disclosed in the '440 patent. In fact, a person skilled in the art would *avoid* applying a polymer of low or no water solubility, i.e., a BOLTORN® polymer, on a water-absorbent particle. Such an application would be expected to decrease the water absorption properties of the particle because a type of barrier layer would be on the particle inhibiting full contact with an aqueous fluid. In contrast, the dedusting agents of the '440 patent are water-soluble, would dissolve upon contact with an aqueous fluid, and hence would not create a barrier between the water absorbent particles and the aqueous fluid, thereby allowing full contact between the particle and an aqueous fluid.

Surprisingly, and unpredictably, applying a dendritic polymer of low to no water solubility to water-swellable polymer particles did not appreciably affect absorption properties, and substantially reduced the amount of fine-size particles, especially after mechanical stress. See Examples 1 and 2, and particularly, Table 1 at page 19.

The examiner further has failed to clearly articulate *facts* as to why the claimed invention "as a whole" would have been obvious to a person skilled in the art. The examiner apparently relies upon each reference teaching a compound having a plurality of a hydroxy groups, and that it therefore would have been obvious to substitute a compound of Hult for a compound in the '440 patent. While the Office Action appears to rationalize its conclusion of obviousness, the examiner does not articulate facts to support the asserted rationale. MPEP §2143.

Furthermore, the '440 patent teaches linear polyols, i.e., an alcohol compound containing a plurality of hydroxy groups. The Hult reference teaches highly branched polyesters having hydroxy groups. Polyesters and polyols differ in structure, reactivity, and properties. Linear polymers and highly branched polymers likewise differ greater in structure, reactivity, and properties, as discussed in the cited Hult reference. Accordingly, the rationale relied upon by the examiner to support a conclusion of obviousness, i.e., simple substitution of one known element to another, is not straightforward, as summarily proposed by the examiner.

In particular, to support a simple substitution rationale, the results of the substitution must be predictable. As set forth above, the present invention provided unexpected results arising from the inclusion of a dendritic polymer with a water-swellable polymer particle, i.e., a reduction in fine-size particles without a reduction in absorption properties.

The Office Action does not articulate any findings that a person skilled in the art could have substituted one known element for another, *and* that the results of the substitution would have been predictable. Therefore, the asserted rationale supporting the §103 rejection does not apply, absent such findings. See MPEP §2143(b).

Accordingly, it is submitted that claim 17 would not have been obvious over the '440 patent in view of the Hult publication, and that the rejection under 35 U.S.C. §103 should be withdrawn. Because independent claim 17 is patentable over the combination of cited references, claims 18, 19, 21, 22, 24-27, 29, and 33 also are patentable under 35 U.S.C. §103.

With further respect to claim 29, an additional basis exists for the patentability of this claim, i.e., the reference fails to recite each claimed element. The examiner relies upon the '440 patent for teaching crosslinking ('440 patent, column 5, lines 1-25). However, the '440 patent discloses internal crosslinking that occurs during polymerization of the water-soluble monomer, which renders the water-absorbent resin water insoluble. See '440 patent, column 5, line 59 through column 6, line 9. This internal crosslinking is different from the *surface*-postcrosslinking step recited in claim 29. Surface-postcrosslinking is a separate step performed *after* the water-swellable polymer particle is prepared and dried, and is fully discussed in the present specification, at page 11, line 41 through page 13, line 4, and is distinguished from internal crosslinking during polymer formation at page 7, line 36 through page 11, line 39. Neither the '440 patent nor the Hult reference discloses surface-postcrosslinking, and accordingly claim 29 is patentable over the combination of cited references for this reason alone.

Claim 23 stands rejected under 35 U.S.C. §103 as being obvious over the '440 patent in view of the Hult reference, and further in view of Short et al. U.S. Patent No. 5,578,119 ('119). Applicants traverse this rejection.

First, claim 23 recites a preferred embodiment of the present invention. Applicants do not rely solely upon the inclusion of hollow microspheres in the water-swellable polymer particles for patentability, but rely upon hollow microspheres and *all* the features recited in claims 17 and 21, from which claim 23 depends. Applicants have addressed the patentability of claims 17 and 21 above, and submit that claim 23 is patentable over a combination of the '440 patent, Hult publication, and '119 patent for the same reasons.

Second, the examiner's reasoning with respect to the '119 patent is faulty. The '119 patent is directed to a sculpting medium containing 10-25%, by weight, of hollow polymeric microspheres, 3-10% thixotropic hydrogel, and 60-80% water. The thixotropic gel contains sodium salts of carboxymethylcellulose and alginic acid ('119 patent, column 6, lines 8-21). The '440 and '119 patents therefore are not in the same field of endeavor. The '440 patent is directed to water-insoluble, crosslinked, absorbent particles. The '119 patent is directed to thixotropic compositions based on water-soluble polymers.

In view of the above, it is submitted that claim 23 would not have been obvious over a combination of the three cited references under 35 U.S.C. §103, and that the rejection should be withdrawn.

Claims 26 and 28 stand rejected under 35 U.S.C. §103 as being obvious over the '132 publication in view of the '440 patent. Applicants traverse this rejection.

The '132 publication and '440 patent have been discussed above. The '132 publication is directed to coating a contact lens with multiple bilayers of polymers. The '440 patent is directed to adding hydrophilic polyols to water-swellable polymers for dedusting. The two references are in no way related.

Furthermore, contrary to the examiner's reasoning, the '132 publication does not teach mixing a hydrogel and a dendrimer. The '132 publication teaches applying a hydrogel layer, than a dendrimer layer, then repeating the process to achieve multiple bilayers

of the polymers. Further, the hydrogel of the '132 patent is dried, but the reference is directed to coatings, *not* particles, as described above.

In addition, the '440 patent teaches drying the hydrogel to form particles (column 6, lines 10-24), then *heat* treating after drying to improve absorbitivity (column 6, lines 25-37). Therefore, the motivation relied upon by the examiner, is incorrect.

In summary, for all the reasons set forth above, and with respect to the other rejections, it is submitted that claims 26 and 28 would not have been obvious under 35 U.S.C. §103 over a combination of the '132 publication and the '440 patent, and that the rejection should be withdrawn.

Claim 30 stands rejected under 35 U.S.C. §103 as being obvious over the '440 patent in view of Hult and further in view of Park et al. U.S. Patent Publication 2001/0038831 ('831 publication). Applicants traverse this rejection.

Claim 30 recites a preferred embodiment of the present invention and applicants do not rely solely on the features recited in claim 30 for patentability. Applicants rely upon the features recited in claims 30 and in claims 29, 26, and 17 form which claim 30 depends. The patentability of claim 17, 26, and 29 have been discussed above, and it is submitted that claim 30 is patentable over a combination of the cited references for the reasons set forth above and that the rejection should be withdrawn.

Claims 17, 19-26, 29, and 30 stand rejected under the judicially-created doctrine of obviousness type double patenting over claims 1-9 and 18-20 of copending U.S. application number 10/589,727. In view of the timely-filed terminal disclaimer filed concurrently with this amendment, it is submitted that this rejection has been overcome and should be withdrawn.

It is submitted that all claims are in a form and scope for allowance. An early and favorable action on the merits is respectfully requested.

Should the examiner wish to discuss the foregoing, or any matter of form in an effort to advance this application toward allowance, the examiner is urged to telephone the undersigned at the indicated number.

Dated: January 13, 2009

Respectfully submitted,

By _____

James J. Napoli
Registration No.: 32,361
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorney for Applicant